PCV8

COMPARATIVE EFFECTIVENESS OF RIVAROXABAN AND STANDARD ANTICOAGULANT THERAPIES FOR PREVENTION OF PRIMARY VENOUS THROMBOEMBOLISM IN PATIENTS UNDERGOING MAJOR ORTHOPEDIC SURGERY

Shewale AR, Martin BC

University of Arkansas for Medical Sciences, Little Rock, AR, USA

OBJECTIVES: Venous thromboembolism (VTE) is one of the major complications after major orthopedic surgeries (MOS). In 2011, FDA approved rivaroxaban for VTE prevention among patients undergoing MOS. The aim of our study is to empirically evaluate the comparative effectiveness of rivaroxaban, warfarin, and low molecular weight heparins (LMWHs) for VTE prevention among MOS patients using "real world" data. **METHODS:** A cohort study using IMS Lifelink Plus (2006-2013) data compared the risk of VTE and major bleed events among MOS patients exposed to rivaroxaban, warfarin, LMWHs, or fondaparinux with those who are not anticoagulated within 7 days after their MOS-hospital discharge. Kaplan Meier curves and Cox proportional hazard models were used to assess the risk of VTE and major bleed events and to adjust for potential confounders. **RESULTS:** A cohort of 35,279 MOS were included which provided 68,340 person years of follow up including 1,004 rivaroxaban, 7,339 warfarin, 5,692 LMWH, 841 fondaparinux exposed patients and 20,403 patients who did not receive an initial anticoagulant. Risk of VTE was lowest for rivaroxaban (H.R.=0.282; 95%CI:0.156-0.510) followed LMWHs (H.R.=0.671 [95%CI=0.582-0.773]), fondaparinux (H.R.=0.680 [95%CI =0.485-0.951]) and warfarin (H.R.=0.872 [95%CI=0.778-0.978]) when compared to no anticoagulant use in unadjusted cox models. After adjusting for potential confounders, only rivaroxaban (H.R.=0.395 [95%CI=0.215-0.742]) and LMWHs (H.R.=0.755[95%CI=0.643-0.873]) significantly reduced the risk of VTE. However, these results were not significant in a sensitivity analysis using a more strict definition to detect VTEs in claims data. There were no bleed events for rivaroxaban users and the risk of bleed events were not significantly different among anticoagulants and non-anticoagulant exposure in both the adjusted and the unadjusted models. **CONCLUSIONS:** LMWHs and Rivaroxaban were associated with reduced VTE events and no detectable increase in major bleeds among MOS patients. These findings, particularly those on major bleed events, should be confirmed in larger study populations.

PCV9

ESTIMATING THE LIFETIME CLINICAL RISK/BENEFITS OF APIXABAN VERSUS EDOXABAN IN NON-VALVULAR ATRIAL FIBRILLATION

Phatak H[1], Dorian P[2], Kongnakorn T[3], Lanitis T[4], Liu X[5], Mardekian J[6], Lawrence J[7], Lip G[8]

[1]*Bristol-Myers Squibb Company, Princeton, NJ, USA,* [2]*University of Torono, Toronto, ON, Canada,* [3]*Evidera, Bangkok, Thailand,* [4]*Evidera, London, UK,* [5]*Pfizer, New York, NY, USA,* [6]*Pfizer Inc., New York, NY, USA,* [7]*BMS, Princeton, NJ, USA,* [8]*University of Birmingham, Birmingham, UK*

OBJECTIVES: This analysis aimed to assess the potential clinical risk/benefits associated with the lifetime use of apixaban versus edoxaban in patients with non-valvular atrial fibrillation (NVAF) in the United States (US). **METHODS:** A Markov model was developed to extrapolate the observed clinical impact of apixaban versus a regimen of edoxaban starting at 60 mg at the lifetime horizon. Outcomes assessed included the number of clinical events avoided for every 1000 patients treated, number of patients needed to treat to prevent one stroke, and number of patients needed to harm with an additional major bleed. Key sources of inputs used to populate the model included: indirect comparison data versus edoxaban from published blinded randomized trials vs warfarin; US life tables for life expectancy; published literature for increased mortality related to outcome events modeled. **RESULTS:** In a cohort of 1,000 patients, treatment with apixaban (at doses used in clinical trials) in comparison with edoxaban 60 mg resulted in 6 fewer strokes and caused 10 fewer major bleeds over the average projected lifetime. This translated in 172 patients needed to treat with apixaban versus edoxaban 60 mg to prevent one stroke with no additional major bleeding. The reduction in clinical events resulted in 29 additional discounted life-years for the cohort of 1,000 patients treated with apixaban. **CONCLUSIONS:** Using an indirect comparison, lifetime use of apixaban is projected to increase life-expectancy versus edoxaban 60 mg QD in the US. It also appears to provide dual risk reduction based on efficacy and safety benefits versus edoxaban 60 mg starting regimen.

PCV10

CARDIOVASCULAR SAFETY WITH THE CONCURRENT USE OF MOOD STABILIZERS OR ATYPICAL ANTIPSYCHOTICS AND STIMULANTS IN CHILDREN AND ADOLESCENTS WITH ATTENTION DEFICIT/HYPERACTIVITY DISORDER AND BIPOLAR DISORDER

Rane P, Bali V, Aparasu RR

University of Houston, Houston, TX, USA

OBJECTIVES: This study compared the cardiovascular safety of the addition of mood stabilizers or atypical antipsychotics to stimulant monotherapy in children and adolescents diagnosed with ADHD and bipolar disorder. **METHODS:** This retrospective cohort study used 2004-2007 IMS LifeLink™ Health Plan Claims Database. Children and adolescents aged 6 to 17 years diagnosed with ADHD and bipolar disorder who initiated a new treatment with stimulants were followed for 12 months to compare the safety of addition of mood stabilizers or atypical antipsychotics to stimulant monotherapy. Only patients who had continuous eligibility 6 months before and 12 months after the index stimulant date were selected. Exposure to a mood stabilizer or atypical antipsychotic agent after the initiation of the index stimulant treatment formed the primary exposure. The primary outcome was defined as the first hospitalization or emergency room (ER) visit for cardiovascular disorder identified using International Classification of Diseases- 9th Revision, Clinical Modification (ICD-9 CM) codes. Cardiovascular risk was compared using time-varying Cox regression analysis adjusting for other cardiac risk factors. **RESULTS:** Of the 1,769 ADHD and bipolar patients, 48.28% were prescribed stimulants only, 16.68% were on mood stabilizer-stimulant combination and 35.05% were on antipsychotic-stimulant combination therapy. The incidence of cardiovascular events were 5.15% in the stimulants-only group, 4.75% in the mood stabilizer-stimulant group and 8.87% in antipsychotic-stimulant group. No statistically significant difference was found in the risk of cardiovascular events among patients with mood stabilizer-stimulant combination (HR=0.98, 95% Confidence Interval, 95% CI: 0.49-1.99) or antipsychotic-stimulant combination (HR=0.57, 95% CI: 0.31-1.05) compared to stimulant monotherapy. **CONCLUSIONS:** The current study did not find any difference in the cardiovascular risk after addition of mood stabilizer or atypical antipsychotic to stimulant monotherapy in patients with ADHD and bipolar disorder. More studies are needed to evaluate overall safety profiles of these therapeutic combinations in patients with comorbid ADHD and bipolar disorder.

PCV11

DISCONTINUATION OF STATIN USE AFTER HEMODIALYSIS AND THE RISK OF CARDIOVASCULAR DISEASES

Liu Y[1], Huang W[1], Chang W[1], Wen Y[2], Tsai Y[1]

[1]*National Yang Ming University, Taipei, Taiwan,* [2]*Chang Gung University, Taoyuan, Taiwan*

OBJECTIVES: Clinical trials showed insignificant effects of statins on preventing cardiovascular diseases(CVD) among hemodialysis patients. This study is to examine the association between discontinuation of statin use after hemodialysis and the risk of CVD. **METHODS:** We conducted a population-based retrospective cohort study using year 1997-2008 National Health Insurance Research Database. We selected patients who are 20 years old or above and first time receiving maintenance hemodialysis. The selected patients were also those prescribed statins at least once in the 180 days before the first hemodialysis. We excluded the patients who had medical history of kidney transplantation or maintenance peritoneal dialysis. Continuous use of statins was defined as receiving prescriptions of statins in the first 90 days after hemodialysis. We used the Cox proportional hazards model to analyze the association between the discontinuation status and the risk of hospitalization or surgeries for coronary heart diseases (CHD) and non-hemorrhagic stroke. The propensity score method was used to adjust the self-selection bias in the statin user and non-user groups. **RESULTS:** Among 8,949 patients examined, 2,079 (23.2%) patients used statins in the first 90 days after hemodialysis. After adjusted by the propensity score, the Cox model showed discontinuation of statin use in the first 90 days after dialysis was not associated with higher risk of hospitalization or surgeries for CHD and non-hemorrhagic stroke (HR 0.55ï¿½, 95% CI 0.50, 0.61) compared to statin users. The results were consistent when stratifying the patients into those with medical history of CVD (n=5288, HR 0.53ï¿½, 95% CI 0.47, 0.60) and those without (n=3661, HR 0.61, 95% CI 0.50, 0.74). **CONCLUSIONS:** Discontinuation of statin use after hemodialysis does not increase the risk of hospitalization or surgeries for CHD and non-hemorrhagic stroke. However, this result cannot rule out the possible association between the severity of hypercholesterolemia or predicted risk of CVD and statin use.

PCV12

THE IMPACT OF RACE ON THE ASSOCIATION BETWEEN A NOVEL GENOTYPE-GUIDED PERSONALIZED WARFARIN SERVICE AND CLINICAL OUTCOMES IN AN ETHNICALLY DIVERSE POPULATION

Manzoor B[1], Duarte J[1], Lee J[1], Galanter WL[1], Walton SM[1], Galanter N[1], Krishnan JA[1], Bauman JL[1], Cavallari LH[2], Nutescu EA[1]

[1]*University of Illinois at Chicago, Chicago, IL, USA,* [2]*University of Florida, Gainesville, FL, USA*

OBJECTIVES: A novel genotype-guided personalized warfarin dosing (PGx) service was implemented at the University of Illinois Hospital & Health Sciences System. The aim of this study was to examine the impact of race on the association between the (PGx) service and anticoagulation related clinical outcomes. **METHODS:** Multivariate linear, logistic, and survival models were used to examine differences across race in the association between the PGx service and several clinical outcomes. These models were adjusted for confounders, and inverse probability treatment weight propensity scoring was used. Our primary outcome of interest was time to first therapeutic INR. **RESULTS:** A total of 339 patients managed by the PGx service (mean age 56±16 years; 61% African-American; 55% female) and 299 historical controls (mean age 54±16 years; 74% African-American, 64% female) were included. In our primary outcome, the treatment effect in time to first therapeutic INR was significantly higher in African-Americans compared to Caucasians (HR: 1.86, 95%CI: 1.3, 2.8 vs. HR: 1.24, 95%CI: 0.4, 3.8, respectively). The treatment effect in time in therapeutic international normalized ratio (INR) range was significantly higher in African-Americans than in Caucasians over the initial 7 days of therapy (β: 5.52 days, 95% CI: 1.4, 9.6 vs. β: 0.78, 95%CI: -9.3, 10.8, respectively). The treatment effect in proportion of INRs at extremes (< 1.5 and > 4) was lower in African-Americans compared to Caucasians (β: -25.56, 95% CI: -31.6, -19.6 vs. β: -22.46, 95% CI: -36.8, -8.2, respectively). Additionally, relative to Caucasians, African-Americans in the PGx group were 2.17 times more likely to have an INR in therapeutic range at discharge (OR: 2.17, 95% CI: 1.0, 4.7). **CONCLUSIONS:** A novel genotype-guided personalized warfarin service was positively associated with anticoagulation related clinical outcomes, and this association was stronger in African-American patients.

PCV14

EHEALTH IN THE MANAGEMENT OF CHRONIC DISEASES: A REVIEW OF PROGRAM EFFICACY

Kiss N[1], Fortier K[2]

[1]*Department of Health Economics, Centre for Public Health, Medical University of Vienna, Vienna, Austria,* [2]*Compass Strategic Consulting, Inc., New Haven, CT, USA*

OBJECTIVES: eHealth is the transfer of health resources, care, and data by electronic means and has the potential to promote reductions in the cost of care. It has been employed by medical professionals to manage chronic diseases outside of a clinical setting, provide useful data for decision making, and deliver timely information and care to the patient. This review assesses the use of eHealth programs in chronic disease management and identifies the settings and patient populations that have resulted in successful outcomes. **METHODS:** A systematic literature review was conducted in Embase, Medline, CINAHL, and PsycINFO. Inclusion criteria were English language studies since 2005 evaluating the efficacy of an eHealth program on patients with chronic disease(s). Studies in which e-mail communication was